Preface

The purpose of this Report is to provide guidance to researchers in preparing protocols that include ionizing radiation exposure to human subjects and to provide guidance to reviewing bodies, such as Institutional Review Boards, in the process of reviewing such protocols. This includes guidance for assessing proper utilization of radiation, estimation of risk, optimization of radiation dose, and formulation of informed consent statements with consistent, comprehensible and accurate language.

These issues have been dealt with in part by previous National Council on Radiation Protection and Measurements (NCRP) reports, which were generally focused on specific issues, modalities, and/or patient populations. Proper utilization, optimization, and/or informed consent were specifically targeted in:

- Report No. 70, *Nuclear Medicine—Factors Influencing the Choice and Use of Radionuclides in Diagnosis and Therapy* (1982);
- Report No. 102, *Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)* (1989);
- Report No. 128, *Radionuclide Exposure of the Embryo/Fetus* (1998);
- Report No. 155, *Management of Radionuclide Therapy Patients* (2006);
- Report No. 170, *Second Primary Cancers and Cardiovascular Disease After Radiation Therapy* (2011);
- Report No. 172, *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States* (2012); and

Many of these concepts apply not only to the procedures encountered in normal standard of care for medical practice but also to human trials involving exposure to ionizing radiation.
Specific NCRP documents have also addressed the issues of radiation biological effectiveness, radiation dose, and risk estimation. Examples include:

- Report No. 96, *Comparative Carcinogenicity of Ionizing Radiation and Chemicals* (1989);
- Report No. 104, *The Relative Biological Effectiveness of Radiations of Different Quality* (1990);
- Report No. 116, *Limitation of Exposure to Ionizing Radiation* (1993);
- Report No. 126, *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection* (1997);
- Report No. 164, *Uncertainties in Internal Radiation Dose Assessment* (2009);

Although the risks of low-level radiation exposure remain controversial, high levels of radiation exposure are well known to cause tissue effects (such as skin burns and epilation) and stochastic effects (such as cancer or second primary cancers).

In this and other reports, the NCRP has considered various alternatives to ionizing radiation for medical procedures. Examples of these applications and their potential health effects include:

- Report No. 74, *Biological Effects of Ultrasound: Mechanisms and Clinical Implications* (1983);
- Report No. 86, *Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields* (1986);
• Report No. 113, *Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms* (1992);
• Report No. 119, *A Practical Guide to the Determination of Human Exposure to Radiofrequency Fields* (1993); and

Other nonionizing radiation techniques, such as thermal imaging (passive mapping of infrared energy from a patient) and transilluminational imaging (transmission of high-intensity visible light through a patient) have not yet been addressed by NCRP.

This Report was prepared by Scientific Committee 4-7 on Evaluating and Communicating Risks for Studies Involving Human Subjects: Guidance for Researchers and Reviewing Bodies. Serving on Scientific Committee 4-7 were:

**Julie K. Timins, Chair**  
New Jersey Commission on Radiation Protection  
Trenton, New Jersey

**Members**

**Jerrold T. Bushberg**  
University of California Davis School of Medicine  
Sacramento, California

**Patricia A. Fleming**  
Saint Mary’s College  
Notre Dame, Indiana

**Linda A. Kroger**  
University of California Davis Medical Center  
Sacramento, California

**Edwin M. Leidholdt, Jr.**  
U.S. Department of Veterans Affairs  
Mare Island, California

**Donald L. Miller**  
U.S. Food and Drug Administration  
Silver Spring, Maryland

**Robert E. Reiman**  
Duke University Medical Center  
Durham, North Carolina

**J. Anthony Seibert**  
University of California Davis School of Medicine  
Sacramento, California

**Steven G. Sutlief**  
Banner MD Anderson Cancer Center  
Gilbert, Arizona

**NCRP Secretariat**

**Michael P. Grissom**, Staff Consultant  
**Cindy L. O’Brien**, Managing Editor  
**Laura J. Atwell**, Director of Operations  
**James R. Cassata**, Executive Director (2012 – 2014)  
**David A. Smith**, Executive Director (2014 – 2016)  
**Kathryn D. Held**, Executive Director (2016 – 2018)
The Council wishes to express its appreciation to the Committee members for the time and effort devoted to the preparation of this Report and to the American Association of Physicists in Medicine, American Board of Radiology Foundation, American College of Radiology, Centers for Disease Control and Prevention (Grant No. 5UE1EH000989), the Society of Nuclear Medicine and Molecular Imaging, and a generous donor for financial support.

John D. Boice, Jr.                                      Kathryn D. Held